Suggestions for Future Study Protocols:
Design and Implementation Improvements

1. Avoid study timepoint terms such as "initiation", "enrollment", "study participation", "prior to the study", "prior to study enrollment", "check-in" unless they are SPECIFICALLY defined elsewhere in protocol. These terms can be variably interpreted. It is simpler and clearer (and thus less likely to lead to inadvertent protocol violations) to use "Screening", "Day -1", "Day -3", or even "confinement".

2. Use "Day 9" instead of "End of Study" (i.e., for an 8-day randomized treatment period, with the close-out of the Day 8 24-h urine and subsequent discharge of subjects occurring the morning of Day 9).

3. Specifically define what procedures should be done for early terminators [i.e., (just) end-of-study (Day 8) safety procedures (and specifically define, i.e., PE, VS, EKG, U/A, clin chem, hematology), or do you want certain biomarkers also obtained, especially if they terminate very late in the study where these might have some relevance (could at least obtain the specimens, and decide later whether to include them in the analysis)].

4. Prior to beginning study, PM representative familiar with site clinical ops in general should closely review final protocol for practicality in implementation [e.g., can multiple close-in-time specimen collection timepoints be condensed, are specific procedures clearly defined for administration and review of questionnaires (who, when, how), are specific procedures clearly defined for specimen collection and processing (e.g., type/composition of containers/lids, desired collection parameters defined [volume, time])]. This should preferably be done at the final draft stage, prior to finalizing the protocol.

5. In addition to routine study monitoring (by an outside organization), PM representative familiar with the specific protocol requirements and site clinical ops in general should monitor the site EARLY in the study (by direct observation, esp. during baseline, prior to any randomized treatment period) for study procedure/specimen processing compliance, esp. for novel/unique procedures/processing (e.g., questionnaires, topography, ABP-Hb adduct spec. processing). That is to say, troubleshoot proactively, not retroactively.

6. Determine a "scientific point person" at the entity that will be writing the study report to have scientific oversight of the results (i.e., scientific interpretation and discussion).

Washed RBC w/ .85% vs .90% saline —
Δ in validation

(1) Print outs of posters
(2) SDS methods
(3) CD-Rom – ABP –

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